Docket No.: ECV-5062CIP2DIV

Response to Office action of 1/24/2008

## AMENDMENTS TO THE CLAIMS

## WHAT IS CLAIMED IS:

1. (Original) A multiple lumen access device for medical uses comprising:

an infusion introducer having an access tube with a proximal end and a distal end for introduction into the body, the introducer including a hub connected to the proximal end of the access tube and a hemostasis valve in a fixed location within the hub that provides a seal around medical implements that are introduced and withdrawn to and from the body through an access tube lumen, the introducer further including a side arm opening distally with respect to the hemostasis valve for infusing a medical solution to the access tube lumen;

a catheter including a catheter tube and a junction housing on a proximal end of the catheter tube, the junction housing having a proximal end and a distal end and including a main channel and at least one auxiliary channel separate from the main channel, both the main channel and the auxiliary channel being in fluid communication with at least one lumen defined in the catheter tube; and

a multi-function adapter having a first unit and a complementary second unit for coupling the catheter to the hub of the infusion introducer such that the catheter tube passes through the hemostasis valve into the access tube lumen, the first unit being attached to the junction housing, and the second unit being fixedly attached to the hub, wherein the first unit may be removably connected to the second unit such that the introducer is converted from an infusion introducer to a multiple lumen access device by virtue of the main channel and the auxiliary channel in the junction housing.

2. (Original) The access device of claim 1 wherein both the main channel and the auxiliary channel extending from the proximal to the distal end of the junction housing, and the main channel and auxiliary channel diverge from the distal end of the junction housing to the proximal end of the junction housing.

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- 3. (Original) The access device of claim 1 wherein the catheter tube includes multiple lumens, one each in fluid communication with the main channel and the auxiliary channel, respectively.
- 4. (Original) The access device of claim 1 wherein the multi-function adapter comprises at least one channel on the first unit and a complementary outwardly extending lug on the second unit for engaging the channel.
- 5. (Original) The access device of claim 4 wherein the multi-function adapter comprises two L-shaped channels on the first unit and two outwardly extending lugs on the second unit for engaging the L-shaped channels.
- 6. (Withdrawn) The access device of claim 1 wherein the multi-function adapter for coupling the junction housing comprises complementary luer threads on the first and second units.
- 7. (Withdrawn) The access device of claim 1 wherein the junction housing includes a device valve therein, the device valve being positioned to provide a seal around devices passed into the main channel.
- 8. (Withdrawn) The access device of claim 7 further including a valve insert housing the device valve and the junction housing includes a cavity open to the main channel for receiving the valve insert.
- 9. (Original) The access device of claim 1 wherein the first unit of the multifunction adapter has a through bore that fits over and is secured to the exterior of the catheter tube.
- 10. (Original) The access device of claim 1 wherein the first unit of the multifunction adapter is rigidly fixed on the distal end of the junction housing.

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11. (Original) The access device of claim 1 wherein the catheter tube has a length sufficient to extend distally from the distal end of the access tube when the catheter is coupled to the hub of the infusion introducer.

- 12. (Original) The access device of claim 11 wherein the catheter is a central venous catheter.
- 13. (Withdrawn) The access device of claim 1 wherein a distal end of the catheter tube terminates in the access tube lumen when the catheter is coupled to the hub of the infusion introducer.
- 14. (Withdrawn) The access device of claim 1 further including a small diameter catheter tube connected to the auxiliary channel of the multi-function adapter, the small catheter tube forming an infusion lumen while a space between the small catheter tube and the access tube lumen defines a device lumen.
- 15. (Original) A multiple lumen access device for medical uses comprising:

  an infusion introducer having an access tube with a proximal end and a distal end for introduction into the body, the introducer including a hub connected to the proximal end of the access tube and a hemostasis valve in a fixed location within the hub that provides a seal around medical implements that are introduced and withdrawn to and from the body through an access tube lumen, the introducer further including a side arm opening distally with respect to the hemostasis valve for infusing a medical solution to the access tube lumen;

a catheter including a catheter tube and a junction housing on a proximal end of the catheter tube, the junction housing having a proximal end and a distal end and including a main channel and at least one auxiliary channel separate from the main channel, both the main channel and the auxiliary channel being in fluid communication with at least one lumen defined in the catheter tube; and Response to Office action of 1/24/2008

a multi-function adapter having a first unit and a complementary second unit for coupling the catheter to the hub of the infusion introducer such that the catheter tube passes through the hemostasis valve and into the access tube lumen, the first unit being rigidly attached to the junction housing and having two L-shaped channels, and the second unit being rigidly attached to the hub and having two outwardly extending lugs for engaging the L-shaped channels, wherein the first unit may be removably connected to the second unit with the lugs in the L-shaped channels such that the introducer is converted from an infusion introducer to a multiple lumen access device by virtue of the main channel and the auxiliary channel in the junction housing.

- 16. (Original) The access device of claim 15 wherein both the main channel and the auxiliary channel extending from the proximal to the distal end of the junction housing, and the main channel and auxiliary channel diverge from the distal end of the junction housing to the proximal end of the junction housing.
- 17. (Withdrawn) The access device of claim 15 wherein the junction housing includes a device valve therein, the device valve being positioned to provide a seal around devices passed into the main channel.
- 18. (Withdrawn) The access device of claim 17 further including a valve insert housing the device valve and the junction housing includes a cavity open to the main channel for receiving the valve insert.
- 19. (Original) The access device of claim 15 wherein the catheter tube has a length sufficient to extend distally from the distal end of the access tube when the catheter is coupled to the hub of the infusion introducer.
- 20. (Original) The access device of claim 19 wherein the catheter is a central venous catheter.

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21. (Withdrawn) The access device of claim 15 wherein a distal end of the catheter tube terminates in the access tube lumen when the catheter is coupled to the hub of the infusion introducer.

22. (Withdrawn) A method for selectively introducing medical devices and infusing a medical solution into a human body through a single entry port, comprising:

inserting an infusion introducer to the vasculature, the infusion introducer having an access tube with a proximal end and a distal end, and a hub connected to the proximal end of the access tube, wherein a hemostasis valve in a fixed location within the hub provides a seal around medical implements that are introduced and withdrawn to and from the body through an access tube lumen, the introducer further including a side arm opening distally with respect to the hemostasis valve for infusing a medical solution to the access tube lumen;

providing a catheter including a catheter tube and a junction housing on a proximal end of the catheter tube, the junction housing having a proximal end and a distal end and a main channel and at least one auxiliary channel separate from the main channel, both the main channel and the auxiliary channel being in fluid communication with at least one lumen defined in the catheter tube;

coupling the catheter to the introducer hub by engaging a first unit of a multifunction adapter on the junction housing to a second unit of the multi-function adapter on the introducer hub such that the catheter tube passes through the hemostasis valve into the access tube lumen;

infusing a medical solution to the vasculature through the side arm and access tube lumen with or without the catheter coupled to the introducer hub; and

infusing a medical solution to the vasculature through the catheter.

23. (Withdrawn) The method of claim 22, wherein the junction housing includes a device valve positioned to provide a seal around medical devices passed into the main channel,

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the method including introducing a medical device through the device valve and through the catheter and into the vasculature.

24. (Withdrawn) The method of claim 23, wherein the catheter tube has a length sufficient to extend distally from the distal end of the access tube when the catheter is coupled to the hub of the infusion introducer, and wherein the medical device passes directly from the catheter tube lumen into the vasculature without entering the access tube lumen.

- 25. (Withdrawn) The method of claim 22, further including simultaneously infusing medical solutions both through the side arm and access tube lumen and through the catheter.
- 26. (Withdrawn) The method of claim 22, further including decoupling the catheter from the introducer hub by disengaging the first and second units of the multi-function adapter, and coupling a different medical device to the introducer hub so that a different catheter tube passes through the hemostasis valve into the access tube lumen.

## Remarks

The remarks below are in response to an Office Action mailed on January 24, 2008. In the Office Action, the drawings were objected to as lacking a hemostasis valve as recited in Claims 1 and 15. In addition, Claims 1-5, 9-12 and 15-20 were rejected under 35 U.S.C. 103(a) over U.S. Pats. Nos. 5,156,596 to Balbierz et al. ("Balbierz") and 5,092,846 to Nishijima et al. ("Nishijima"). Finally, Claims 1-5, 9-12, 15-16 and 19-20 were rejected under obviousness-type double patenting over U.S. Pats. Nos. 6,827,710 and 6,592,544.

With respect to the double-patenting rejection, without conceding the appropriateness of the rejection and for expedient prosecution, a terminal disclaimer is enclosed disclaiming any term over the commonly assigned U.S. Pats. Nos. 6,827,710 and 6,592,544. The double-patenting rejection has therefore been overcome.

Applicant's attorney disagrees with the objection that the drawings fail to depict a hemostasis valve. Several figures depict such a valve, such as the valve 70 in Figure 1 of the

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